MAY - 8 2001

K010542

510(k) Summary of Safety and Effectiveness

Submitter:	Surgical Navigation Specialists Inc.
Address:	6509 Airport Road Mississauga, Ontario Canada L4V 1S7
Contact:	Carol Nakagawa, Manager of Regulatory Affairs
Telephone:	(905) 672-2100
Date:	February 21, 2001
Trade Names:	SNN System including the TomoGuide Option and TomoGuide
Common Name:	Image-Guided Surgical System.
Classification Name:	Stereotaxic Device.
Predicate Devices:	SNN System K982570 and K993673; and UltraGuide CT-Guide 1010 K002258.
Device Description:	The TomoGuide Option is an option of the SNN System which provides image-guided navigation based on an intra-operative/interventional CT image of the patient anatomy.
Intended Use:	The SNN System is intended to provide computer assisted planning and/or navigation information for either open or percutaneous clinical situations. Diagnostic images of the patient are used to plan, localize, and navigate surgical or interventional instruments, assisting the qualified medical professional before and/or during clinical situations.
Comparison to Predicates:	The intended use and technological characteristics of the SNN System including the TomoGuide Option are substantially equivalent, in the opinion of SNS Inc., to those of the predicate devices and do not pose any new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Surgical Navigation Specialists, Inc.
c/o Ms. Carol Nakagawa
Manager of Regulatory Affairs
Cedara Software Corporation
6509 Airport Road
Mississauga, Ontario
Canada L4V 1S7

Re: K010542
Trade/Device Name: SNN System including the TomoGuide Option
Regulation Number: 882.4560
Regulatory Class: II
Product Code: HAW
Dated: February 21, 2001
Received: February 23, 2001

Dear Ms. Nakagawa:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010542

Device Name: SNN System including the TomoGuide Option

Indications For Use :

The SNN System is indicated for use in:

- neurological (cranial and spinal), ENT (ear, nose and throat), and orthopaedic surgical procedures, such as tumor resections, biopsies, endoscopies, screw placements, bone fractures and sinus procedures;
- clinical interventions such as needle biopsies, fluid drainage or aspiration;
- frame-based stereotaxic procedures such as biopsies, functional stereotaxy, tumor resections, vascular malformation surgeries, thalamotomies and pallidotomies.

The SNN System is intended to provide computer assisted planning and/or navigation information for either open or percutaneous clinical situations where a reference to a rigid anatomical structure such as the skull, long bone, or vertebra, can be identified relative to a CT, MR, fluoroscopic, or other medical image of the target anatomy.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010542